DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 23, 2016

Mdoloris Medical Systems SAS
% Thomas Kroenke
Principal Consultant
Speed to Market, Inc.
PO Box 3018
Nederland, Colorado 80466

Re: K142969
Trade/Device Name: Mdoloris Medical Systems SAS HFVI Monitor
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: January 11, 2016
Received: January 14, 2016

Dear Thomas Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

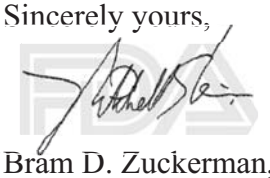
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142969

Device Name
Mdoloris HFVI Monitor

Indications for Use *(Describe)*
The Mdoloris Medical Systems SAS HFVI Monitor is intended to acquire, display, and analyze electrocardiographic information and to measure-heart rate variability (HRV). These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submission Date:	28 January 2016
510(k) Number:	K142969
Submitter:	Mdoloris Medical Systems SAS 270 rue Salvador Allende 59120 Loos France
Submitter Correspondent	Mrs. Mathilde Collet Mdoloris Medical Systems SAS Phone: +011 33 3 62 09 20 81 Fax: +011 33 9 72 38 75 27 Email: mathilde.collet@mdoloris.com
Application Correspondent:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	Mdoloris Medical Systems SAS 270 rue Salvador Allende 59120 Loos France
Trade Name:	Mdoloris HFVI Monitor
Common Name:	Heart Rate Variability Monitor
Classification Name:	Electrocardiograph
Classification Regulation:	21 CFR §870.2340
Product Code:	DPS

Substantially Equivalent Devices:	*New Mdoloris Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Mdoloris Medical Systems SAS HFVI Monitor	K071168	DyAnsys, Inc. The Portable ANSiscope™

510(k) Summary

Device Description: The Mdoloris Medical Systems SAS (Mdoloris) HFVI Monitor is a heart rate variability monitor intended for use in a medical environment and under the direct supervision of a licensed healthcare practitioner or by personnel specifically trained for its use. The HFVI Sensor acquires electrocardiographic (ECG) signals from the patient, and the Mdoloris HFVI Monitor analyzes the ECG information using a proprietary algorithm that results in the calculation of the High Frequency Variability Index (HFVI).

The HFVI is a measure of heart rate variability (HRV), and has a value between 0 and 100.

It is intended for use on adult and pediatric patients.

Intended Use: The Mdoloris Medical Systems SAS HFVI Monitor is intended to acquire, display, and analyze electrocardiographic information and to measure-heart rate variability (HRV). These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.

Technology Comparison: The Mdoloris HFVI Monitor employs the same technological characteristics as the predicate device.

Characteristic	*Predicate Device*	*Proposed Device*
Displayed Parameters	Real-time ECG waveform Real-time heart rate Real-time sympathovagal balANS (from -50 to 50) Real-time sympathetic ANS_i index (from -50 to 50) Real-time parasympathetic ANS_i index (from -50 to 50) ECG lead selection Dysfunction Static balANS Percent of dysfunction	ECG graph (not for diagnosis) Instantaneous HFVI Medium trend HFVI HFVI graph Filtered RR Series Energy Index value Signal quality indicator (color indicator of Energy Index)
Number of Electrodes	Three (3) for HRV One (1) for grounding Chest lead for ECG functionality	Three (3) for HRV

510(k) Summary

Characteristic	*Predicate Device*	*Proposed Device*
Type of Analysis	Separation of sympathetic and parasympathetic components of the Autonomic Nervous System (ANS) by scale covariance approach Sympathetic response is real part of complex wave function Parasympathetic response is imaginary part of complex wave function	R-R series artifacts removal R-R series re-sampling Normalization of the signal

Summary of Performance Testing:

Software

The Mdoloris HFVI Monitor software was designed and developed according to a robust software development process, and were rigorously verified and validated. Software information is provided in accordance with internal requirements and the following guidance documents:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99; and*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*

Test results indicate that the Mdoloris HFVI Monitor complies with its predetermined specifications and the guidance documents.

Electrical Safety

The Mdoloris HFVI Monitor was tested for patient safety in accordance with the following standards:

- *IEC 60601-1: 2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Test results indicated that the Mdoloris HFVI Monitor complies with the applicable Standards.

Electromagnetic Compatibility

The Mdoloris HFVI Monitor was tested for EMC in accordance with the following standard:

- *IEC 60601-1-2: 2007, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.*

Test results indicated that the Mdoloris HFVI Monitor complies with the applicable Standard.

510(k) Summary

Performance Testing – Bench

The Mdoloris HFVI Monitor was tested for performance in accordance with internal requirements and the following standard.

- *AAMI EC12: 2000, Disposable ECG Electrodes;*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices; and*
- *ISTA Procedure 2A, Partial simulation performance test procedure – Packaged-products 150 lb (68 kg) or less.*

Test results indicated that the Mdoloris HFVI Monitor complies with internal requirements and the applicable Standard.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to the Mdoloris HFVI Monitor. The results of these activities demonstrate that the Mdoloris HFVI Monitor is as safe, as effective, and performs as well as or better than the predicate device.

Therefore, the Mdoloris HFVI Monitor is considered substantially equivalent to the predicate device.